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Development of an item pool for a needs-based measure of quality of life of carers of a family member with dementia

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Compliance with ethical standards

Jan Oyebode, Penny Wright, Simon Pini, Mike Horton, each declare that this work was supported by the Medical Research Council (MRC) and the National Institute for Health Research (NIHR). Grant title: HQLC Dementia Carers Instrument Development: DECIDE (MR/M025179/1) and that the grant is registered on the UK Research and Innovation Gateway: http://gtr.ukri.org/projects?ref=MR/M025179/1 . They also declare that they have received financial support for travel to meetings for the study, manuscript preparation or other purposes from the grant funder as part of the award only. In addition, Penny Wright has declared that she is the principal investigator and was the main applicant for the funding that was received from the MRC and NIHR, and Jan Oyebode has declared her position as a co-investigator. The following authors have no conflicts of interest to declare: Emma Ingleson, Molly Megson, Linda Clare, Hareth Al-Janabi, Carol Brayne.

All authors contributed to the overall study design and reviewed and approved the paper. MM, EI and SP collected the data and contributed to analysis. JO wrote the paper with help from PW and SP.

Ethical approval was given in November 2015 by a UK National Health Service ethics committee. Informed consent was obtained from all individual participants included in the study.

Abstract

Purpose
This paper describes the development of an item pool for a needs-based self-report outcome measure of the impact of caring for a relative, friend or neighbour with dementia on carer quality of life. The aims are to give a detailed account of the steps involved and describe the resulting item pool.
Methods
Seven steps were followed: generation of an initial item set drawing on 42 needs-led interviews with carers, a content and face validity check, assessment of psychometric potential, testing of response formats, pre-testing through cognitive interviews with 22 carers, administration rehearsal with 2 carers, and final review.
Results
An initial set of 99 items was refined to a pool of 70 to be answered using a binary response format. Items were excluded due to overlap with others, ceiling effects, ambiguity, dependency on function of the person with dementia or two-part phrasing. Items retained covered a breadth of areas of impact of caring and were understandable and acceptable to respondents.
Conclusions
The resulting dementia-carer specific item pool reflects the accounts of a diverse sample of those who provide care for a person with dementia, allowing them to define the nature of the impact on their lives and resulting in a valid acceptable set of items.

Key Points for Decision Makers

- Dementia, and interventions for dementia, affect not only the patient but also family carers and therefore clinical decision-making needs to be informed by impacts on carers' quality of life as well as that of patients.
- The needs-based approach, used in this study, is a valuable person-centred approach on which to base measures of quality of life. The approach suggests that a person's quality of life is affected by a condition insofar as that condition affects the person's ability to fulfil his or her needs.
- Between establishing needs and developing a carer-reported measure of quality of life come several steps that must be rigorously followed if a valid and useful measure is to be developed. This paper describes these steps.

1 Introduction

Despite evidence to suggest decline in the incidence of dementia in Europe, there is a likelihood that overall prevalence will remain relatively static as the population ages [1]. In the UK it is estimated that by 2025 over one million people will be living with dementia [2]. Most are supported by informal carers, those who provide care for a relative, friend or neighbour, who cannot cope without their support [2,3]. Carers are estimated to contribute annually the equivalent of between £1.34 billion [4] and £13.2 billion [5] worth of unpaid hours of care in the UK alone. Therefore, maintaining carer quality of life (QoL) is not only important for individual carers and those cared for, but also for society.

In this context, an increasing number of interventions are aimed at improving quality of life of dementia carers [6], however there is no single widely accepted measure of dementia carers' quality of life. Self-reported outcome (SRO) measures for QoL must be 'fit for purpose' both in terms of their descriptive system (defining relevant content) and their corresponding valuation system (psychometric and econometric). They may be uni- ot multi-dimensional. The advantage of a multi-dimensional measure is that more than one 'construct' can be evaluated, thereby offering a 'profile' which may be useful in economic evaluation. However, they tend to be longer and therefore more burdensome to complete than uni-dimensional measures. If the final item set is intended to be brief, the precision and responsiveness of a unidimensional measure will be maintained but likely reduced for a multidimensional measure. From the large number of varied SROs available to assess aspects of dementia carer QoL there is no agreement about which, if any, delivers the standards required across both the descriptive and valuation systems [7-10]. A recent review of outcome measures, including of QoL [8], identified 32 QoL measures that had been used in dementia carer research. The four most commonly used were the Short Form-36 [11], the EuroQoL (EQ-5D) [12], the World Health Organisation Quality of Life – Bref (WHOQOL-BREF) [13] and the Health Utilities Index Mark [14], none of which is specific to dementia carers. The authors recommend instruments specific to dementia carers should be used in outcome research alongside generic measures due to their greater sensitivity to specific changes. A systematic review [7] adhering to COSMIN methodology [15] identified ten measures used with dementia carer samples. Three of these measures were developed specifically for dementia carers, but two lacked evidence to recommend use [16,17] The third, Impact of Alzheimer Disease on Caregiver Questionnaire [18], is a unidimensional scale with fair to excellent psychometric qualities. However, further evaluation was advised including extending the sample to an older age group and to include carers of those with dementia other than Alzheimer's disease.

The CarerQoL [19] was specifically developed to measure care-related, rather than health-related or general, QoL in economic evaluations. It aims to capture a description of the caring situation through the use of seven questions reflecting dimensions found in pre-existing scales of carer burden, as well as providing an index of valuation on a visual analogue scale. The scale's applicability to dementia carers is untested as it has not been specifically used in dementia care studies. The initial validation sample [19] was heterogenous, including a substantial proportion (28%) of parents, who would be highly unlikely to be carers for those with dementia. A later study of the scale's psychometric properties [20] involved carers of older people. However, care recipients'

conditions were unspecified and generalisability is limited as all were in receipt of care from a single long-term care facility in the Netherlands, 74% being resident there.

In response to the lack of suitable measures, in 2014, the British Medical Research Council (MRC), called for research to design a new measure of quality of life of dementia carers to be developed inductively, within a conceptual framework and using gold standard psychometric techniques. In this paper, we report on development of an item pool for a new SRO measure of dementia carer quality of life, conducted as part of the Dementia Carers Instrument Development (DECIDE) study, which was funded through the MRC call.

The conceptual framework adopted was the needs-based approach. This was identified as suitable for our task, as it is fully inductive, positioning the lived experiences of the target population as central to measure development, rather than generating items from previous research. The needs-based approach sees QoL as being attained to the degree to which a person is able to fulfil his or her human needs [21,22]. Caring for someone with dementia has far-reaching effects and therefore can affect needs fulfilment and QoL. Even though the majority of carers gain satisfaction and many experience a sense of mastery or fulfilment [23], the tasks involved may lead to fatigue and financial consequences, and detract from time for work, sleep, leisure, and other relationships [24]. Almost 75% of carers report grieving for lost aspects of their relationship [25,26], 20-33% report clinically significant depression [27,28] and 61% report their health has suffered [29]. Consistent with needs-based theory, needs-based measures [e.g. 30-32] are concerned with the ways that a person's life is affected by a condition, that is, they focus on the outcome (QoL) rather than condition-related influences on QoL, as might be the case for health-related quality of life measures [33]. The gold standard steps for development of a needs-based quality of life SRO measure include four phases: qualitative interviews, item generation, formatting (nature of item statements, number of response options) and field testing (for face and content validity) [34]. These are followed by assessment of psychometric properties These steps concur with those generally recommended in modern psychometrics [35]. However, it is noted that, in many papers, little detail is given of the individual development steps. This paper provides an account of the development of the item pool for a new needs-based SRO measure (or measures) of the impact of caring for a relative with dementia on carer QoL. The new scale(s) is named SIDECAR (Scales measuring the Impact of DEmentia on CARers) and this title is used in the text that follows. In focusing on the early stages of development, our aims are two-fold: to describe the development of the item pool and to give insight into the development process.

2 Method

2.1 Procedure

Ethical approval for the study was given in November 2015 by a UK National Health Service ethics committee. Following this, a number of developmental steps were followed, consistent with the four steps described by Hunt and McKenna [34], outlined above. The process was adapted in three ways: (i) to include two iterations of validity testing, (ii) to separate item generation into item generation and item reduction, (iii) to add a step of field-testing for acceptability and feasibility. Each step, its purpose and the method used are outlined in figure 1

and more detail is given below. Informed consent was obtained from all participants in the study. The grant is registered on the UK Research and Innovation Gateway: http://gtr.ukri.org/projects?ref=MR/M025179/1

INSERT FIGURE 1 ABOUT HERE

2.2 Qualitative interviews

Semi-structured interviews, designed to elicit ways that caring impacted upon carers' lives, were conducted with carers supporting a relative with dementia in the community. Carers needed to be aged 16 years or older, have capacity to consent and be able to understand English. Purposive sampling was used to ensure variation in age, ethnicity, gender, relationship to person with dementia, rurality, and co-residence with person cared-for. Participants were recruited from an NHS organisation (Bradford District Care NHS Foundation Trust), two charitable organisations (Carers Leeds: a local organisation supporting carers; the Alzheimer's Society: the major UK national charity for dementia) and through participants passing on the project details to other carers known to them. An initial approach was made by a person from a recruiting organisation involved in potential participants' support, or they responded directly to the research team using contact details displayed on fliers. A member of the research team then contacted the prospective participant to check eligibility, provide further information, answer questions and arrange a time to visit, take consent and interview. Interviewees could be seen at home or in a service-based setting. The interviews, which were audio-recorded, focused on finding out about the ways that caring impacted on quality of life by asking about rewarding and challenging experiences of caring and related thoughts, feelings and experiences. (The semi-structured interview schedule can be seen in openly available material supplementary to Pini et al. [36]). Recordings were professionally transcribed, then safely deleted and personal details in transcripts were changed to protect confidentiality.

2.3 Generation of initial item set

Anonymised transcripts from the qualitative interviews were used to generate the initial item set. Each transcript was examined by one of the research team (SP, EI, MM), who extracted all phrases used by carers to describe the impact of caring on their lives, with a view to comprehensively capturing key areas. A second member of the team checked this process for reliability across 10 transcripts. To enable the process of linking from key phrases to items, the researchers (SP, JO, PW, EI) grouped those with similar content together, using N-Vivo software [37] to manage the data. This provided an easy overview of excerpts that reflected similar impacts. Phrases were then embedded in first person and current tense, to create draft items which drew on the words and expressions used by the participants (see table 1). Pros and cons of including both positively and negatively worded items were discussed within the wider research team and project advisory board. There were measurement advantages, from psychometric and valuation perspectives, from all items being posed in the same direction but from a clinical and carer perspective it was felt important to include positively as well as negatively directed items should these appear in the interview scripts. The trade-off of direct carer experience, against potential impact on the measurement properties, was considered worthwhile, in order to accentuate the truest reflection of carer experience and ensure that carers could relate to the items.

INSERT TABLE 1 ABOUT HERE

2.4 Initial content and face validity check

Suggestions to improve comprehension, ambiguity and relevance of the items were put forward by the core research team (SP, PW, JO, EI), the wider research team (MH, LC, HA-J), two carer consultants to the project and a project partner (Carers Leeds: a local organisation supporting carers). The two carer consultants had been invited to become study consultants by Carers Leeds in recognition of their potential to contribute an 'expert-by-experience' perspective. Suggestions were reviewed and discussed by the core research team and consensus reached on any changes.

In parallel with generation of the item pool, the researchers also conducted a separate thematic analysis [38] of the qualitative interviews to derive a needs-led framework of the impact of dementia care upon fulfilment of carers' needs. This was not conducted to inform scale development, but was a separate piece of work, fully described elsewhere [36]. The framework was iteratively developed with the final version capturing the way caring impacted on the fulfilment of nine needs: Being a carer impacts on fulfilling my need to feel in control of my life; to feel close to the person I care for; to be my own person; to feel connected to the people around me; to take care of myself; for freedom; to protect the person I care for; to get things done and to share/express my thoughts and feelings. There were two useful points of connection between the thematic analysis and the item development (see here and 2.8 below). At this stage we checked the items for spread against the themes of the needs-led framework. This enabled us to be more confident that the item pool comprehensively reflected all key areas of impact of caring on quality of life (see table 1).

2.5 Item reduction 1

In order to maximise the measurement range of the item set, we aimed for the item pool to include some items that were likely to be endorsed by almost every carer, some that very few carers would endorse and some likely to fall at each step between these extremes. To do this, we placed each item on a hypothetical 'ruler' of carers' needs-based quality of life. Placement was informed by (i) the frequency with which content of an item had been mentioned across the qualitative interviews, (ii) whether the item content had been mentioned across the diversity of carers who had been interviewed and (iii) the comments made by the carer consultants.

2.6 Field-testing for content and face validity and response format

2.6.1 Participants for cognitive interviews

Cognitive interviews [39] were used to field test the items. Participants were purposively recruited to ensure variation by age and education, known to affect test performance [40], and ethnicity (white British, black British, South Asian) to reflect major ethnic groups in the UK population) since this affects language use and acceptability. To meet the requirements of the purposive sampling strategy we aimed to recruit up to 24 participants. It has been found that the chance of identifying significant problems with items decreases with the sample size [41]. Our anticipated sample size was larger than the number of 5-15 recently recommended [42]

giving confidence that we would have sufficient to identify any major issues. We aimed for roughly equal numbers of participants new to the study and participants who had taken part in the earlier qualitative interviews. Inclusion of the latter group allowed some cognitive interviewees to comment on whether or not the item pool reflected issues they had spoken about at interview, a strategy that adds to content validity [43]. Carers were eligible if they were aged over 16 years and cared for a relative with a diagnosis of dementia and were recruited through the three organisations described in 2.2 above.

2.6.2 Procedure for cognitive interviews

The cognitive interviews involved each participant reading out each item and describing aloud the thought process leading to their answer. The aim was to give the researchers insight into the way each item was understood [39], considering four issues related to each question (ease of understanding, clarity of meaning, perceived usefulness, ability to use a Yes/No response format). A sheet was used for the interviewer to enter a tick or cross for each of these four attributes for each question, as well as offering space to note participants' comments or suggestions for re-wording. While these potential sources of confusion were predefined, probes were spontaneous dependent on the reaction of the participant rather than scripted [42]. We anticipated that the full set of items drawn from the interviews might be considerable and therefore adopted a strategy to keep burden manageable: Items would be divided into three groups reflecting those judged to be most straightforward, intermediate and most contentious in terms of comprehension and sensitivity of subject matter. All cognitive interviewees would complete the most problematic items, as it was important to have full feedback on these. The 'straightforward' items would be divided into sub-sets with half the interviewees completing one sub-set and the other half completing the alternative sub-set. The medium complexity items would be divided into three subsets, with a third of the cognitive interviewees completing each subset. In summary, items anticipated as more straightforward or of medium complexity would be completed by fewer participants.

In addition, at this stage, response formats were considered. Binary and Likert formats were considered by the research team: a 4-option Likert scale (Strongly Agree – Strongly Disagree) would produce more information since these contain more measurement points than a dichotomous format. On the other hand, a binary format (Yes/No) would produce scores that would be more reliable, as they would be less susceptible to variable interpretation by the respondents of the boundaries between the response options. A binary format would also maintain consistency with disease-specific quality of life scales that have followed the needs-led approach [30-33] and would transfer more readily for valuation aspects of the study. As there were pros and cons to each format and as it was crucial for carers to be able and willing to respond to items, it was decided to make a final decision based on user preferences. Each participant in the cognitive interviews was therefore invited to answer 12 items using both a binary format and a Likert scale and was asked which format they preferred. Sequence of presentation of the formats was alternated between participants to minimise any order effects.

2.7 Administration, acceptability and feasibility testing

Instructions for administration were drafted by two researchers (SP, JO) and agreed across the core research team and with the carer consultants. Following this, two rehearsal interviews were conducted in which two new participants completed the entire item pool, reading the instructions and completing the items without interruption to test for overall coherence and timing.

2.8 Item reduction 2

A final review by the research team was undertaken with the aim of reducing the item pool to a maximum of 70; a number considered by our carer advisors and carer consultants as an acceptable length for larger scale testing. To inform item removal, the team considered: (i) cognitive interview feedback (to remove any items with persisting ambiguity and those where responses appeared heavily dependent on external factors); (ii) spread of items (to retain items related to all nine themes of the thematic analysis); (iii) inter-item correlations (to reduce redundancy from overlap); (iv) ceiling and floor effects (where all respondents endorsed/or did not endorse the item); and (v) removal of any two-part items.

3 Results

Key demographic characteristics of the qualitative interview sample are shown in table 2. In addition, the sample had been caring an average of 54 months (range 5-180), 33 were co-resident with the person cared for, diagnoses of those cared for were Alzheimer's disease (18), vascular dementia (13), other dementia (9), type not known (2). Twelve of the people with dementia could not be left alone, 24 could be alone for up to half a day and seven for a whole day. Forty-one carers were interviewed at home and one at their place of work. Interviews lasted on average 77 minutes (range 23-150).

Ninety-nine potential items were generated from the transcripts, with every aspect of the thematic framework represented. In addition to embedding expressions used by carers themselves in the items, as intended, words were paraphrased where an expression was colloquial and might not be widely understood. ~~In addition,~~ Some items were added which voiced implied but unsaid issues that may have been taboo to be mentioned more openly by interviewees. As a result of the initial content and face validity check, 15 items were reworded to improve general clarity, for example, paraphrasing participants' words to circumvent colloquialisms; one two-part question was split into its two component parts; three items were collapsed into one ("I have been given clear information about support available to me as a carer"); and 5 items were added reflecting implied but unsaid issues (e.g. " I fear what might happen if I am honest with services." "I often lose my temper with the person I care for."). The revised item pool now had 103 items. Placing the 103 potential items on the hypothetical 'ruler' resulted in 11 items being removed (item pool now 92). Checking the distribution across the nine themes of the needs-led framework revealed that there was still at least one item in the pool linked with each theme.

Following this initial preparation, the items were tested across twenty-two carers who participated in cognitive interviews. Ten were new to the study and twelve had taken part in the initial qualitative interviews. (See table 2 for sociodemographic details).

INSERT TABLE 2 ABOUT HERE

Following the strategy outlined in 2.6.2, two of the research team (JO, SP) met to assign items to the problematic, straightforward or intermediate categories. Judgements were informed by subject matter (e.g. "The

stresses of caring make me think about harming myself"), possible difficulty in comprehension (e.g. "Receiving help is more hassle than it is worth") and items where it had been difficult to capture a particular experience succinctly (e.g. "Having to trick the person I care for into doing things makes me feel bad").
Twenty-eight of the items were judged 'straightforward', 16 likely to be problematic and 48 as intermediate. All 22 cognitive interviewees were presented with 46 of the 92 items (16 problematic, 14 straightforward, 16 intermediate). Every item was responded to by at least 7 interviewees and items anticipated as more straightforward or intermediate were completed by fewer participants.

Following the first eight cognitive interviews the research team reviewed the feedback. It was noted that the "Yes/No" response format was creating ambiguity in responses to some questions. For example, both Yes and No appeared to endorse the item "I am not in control of my emotions" ("Yes, I am not in control" and "No, I am not in control"). To solve this, the response wording was changed to "Agree/Disagree". ("I agree with 'I am not in control' " vs "I disagree with 'I am not in control' "). Changes to wording were also considered if more than one respondent highlighted a similar problem with an item. This resulted in three items being reworded.

Following a further eight interviews the research team again reviewed the responses. One item was removed because it caused confusion and could not be adequately reworded; six items were reworded; and two were changed from single items for friends/family into separate items for friends and family respectively. Finally, six further interviews were conducted, resulting in one more item being removed and another reworded. As we had covered key attributes outlined in the purposive sampling strategy and no new issues were raised in interviews 21 and 22, recruitment ceased at this point.

This resulted in an item pool of 92 items, all of which were acceptable to the participants. The binary response format was adopted in accordance with the majority view (14/22 respondent), in keeping with other needs-based QoL measures [19-21], and maximising fit with later aspects of the study.

Two rehearsal interviews were conducted with two new participants (white British female spousal carers, aged 65 years +, who had left school at the minimum leaving age, one from an urban and one from a rural area). Neither participant found it difficult or distressing to complete the entire item pool. Both completed the vast majority of items without asking for extra information or clarification (2 and 4 queries respectively). Finally, twenty-two items were removed to reduce the item pool from 92 to 70 items. Reasons for removal of items were: redundancy due to overlap (7), ceiling effects (2), floor effects (0), two-part questions (13, ambiguity (4), dependent on the function of the person with dementia (2), not carer specific (1) (some items were removed for more than one reason, see supplementary material for details). Table 3 shows the 70 items included in the final pool.

INSERT TABLE 3 ABOUT HERE

4. Discussion

The primary aim of this report was to describe the nature and development of a needs-based PRO item pool to take forward into a larger-scale psychometric study. This will provide data for Rasch analysis and allow development of one or more short uni-dimensional carer-reported outcome measure(s) of dementia carers' quality of life. In the next stages, the SIDECAR item pool will undergo psychometric testing including Rasch analysis to derive an item bank and a short SRO measure, which will be subject to valuation studies. Additionally, the pool has potential to provide items for parallel forms and provides a set of acceptably worded items on carer quality of life that could be used as a basis for comprehensive assessment of carers' needs to inform support or interventions.

In line with the needs-based approach, the items were grounded in the experience of a diverse sample of UK-based family carers of people with dementia and were not based on prior theory or research. The generation of the items directly from the interview transcripts complies with FDA guidelines for scale generation [44] while preserving the lived experience of carers, as well as, where possible, their words. The face validity and cognitive interview processes enhanced acceptability and understandability. The checks for content validity and psychometric suitability ensured relevance to carers and usefulness to researchers. The process of development followed widely used steps, with expansion of the stages of item generation and reduction, and testing of face and content validity, to ensure rigour of the item pool and new measures to be developed from it.

Many questionnaires of QoL in dementia carers are generic rather than specific, or are multi-domain scales [9], whereas the item pool described here is specific to dementia carers and reflects a wide range of impacts but without explicit division into domains. Two of the seven carer QoL scales reviewed by Dow et al [9] were dementia specific but only one of these [17] was grounded in carer accounts from focus groups, conducted with diverse groups in the USA. The approach taken to development of that scale was multi-trait scaling, whereas we took a needs-based approach. One strength of the SIDECAR item pool is its derivation from interviews with a purposively sample of diverse dementia carers with different caring contexts. The item pool gains validity from this sampling strategy.

The work has a number of limitations. We were unable to include friends and neighbours as carers in the participant samples, had few carers from rural settings, and all participants were UK based, so limiting generalisability.

5. Conclusion

In this paper, we have described the development of a 70-item pool for a needs-based SRO measure of carer quality of life, giving a degree of detail that may be of interest to researchers interested in developing needs-based SRO scales. The dementia-carer specific item pool reflects the accounts of a diverse sample of those who provide care for a person with dementia, allowing them to define the nature of the impact on their lives and resulting in a valid acceptable set of items.

Data Availability Statement

The University of Leeds will make a link to the published study available through the White Rose repository.

The datasets generated and/or analysed during the current study are available from https://doi.org/10.5518/375

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Figure 1: Flowchart to show steps in the development of the item pool

Step	Purpose	Method
Qualitative interviews	To derive the item pool inductively from carer accounts	Semi-structured interviews with 42 carers purposively sampled for diversity.
Generation of initial item set	To generate items relevant and understandable to dementia carers	Statements identified in transcripts indicating how needs fulfilment was affected by dementia care. Carers' words retained where possible
Initial content and face validity check	To gain a subjective judgement of whether items were reflective of the primary data, were well worded and appeared to measure the correct construct	Consultation within team of six researchers, two carers and a charitable sector carers' organisation
Item reduction 1	To sift proposed items for potential ability to provide a useful contribution to measurement	Placement of each item on a hypothetical 'ruler' of carers' needs-based quality of life using information from the 42 interviews and carer panel feedback
Field testing for content and face validity	To assess whether items carried the intended meaning for respondents and could be answered using the response options offered.	Cognitive, think aloud interviews with the same sample of 22 carers as field testing of response format.
Field testing for response format	To ensure format was usable by respondents and would yield meaningful answers	Debate in research team and majority preference from a sample of 22 carers (12 who had taken part in step 1 interviews and 10 newly recruited)

Acceptability and feasibility testing	To assess acceptability of time taken to administer the whole item pool and check for any order effects.	Rehearsal for administration with two newly recruited carers under 'test conditions'
Item reduction 2	To reduce the large pool of acceptable items to a smaller number that would be acceptable in a larger scale psychometric study.	Review by research team for: overlap, ceiling effects, two-part questions, ambiguity, and dependency on the function of the person with dementia.

Activities under completion, to be reported in future		
Psychometric testing	To undertake psychometric evaluation of the item pool using Item Response Theory followed by application of Classical Test Theory, to evaluate the psychometric properties if the scale	Study of carers of people with dementia from across England and Wales who will complete the item pool plus other questionnaires at three time-points. Data will be analysed following COSMIN guidance [10]. Assessments will include Rasch analysis, test-retest reliability, convergent validity and responsiveness to change.
Valuation studies	To generate indicators for SIDECAR use in valuation from both a carer and general public perspective	Estimation of the relationship between items from SIDECAR and the utility-weighted index form of EQ-5D. Direct elicitation of preliminary values for the SIDECAR items using DCE methods with a sample of carers and a corresponding general population sample .

COSMIN: Consensus-based Standards for the selection of health Measurement Instruments
DCE: Discrete Choice Experiment

Table 1: To show links between draft items, extracts from transcripts and needs-led themes of quality of life.

Example item	**An associated interview extract (number indicates identity code of transcript)**	**Needs-led theme connected with the item**
Caring has given me a purpose in life	"Purpose. Until my mother's diagnosis I had no purpose at all. I had no purpose at all." (32)	Be my own person
I find it hard to understand how dementia affects the person I care for	"Because it's so difficult to understand this illness that you just don't know whether you're doing the right thing, you know, whether it's right or wrong, you just don't know, and all of a sudden when somebody tells me that, "Oh, he's got Alzheimer's, you need to understand," it's very difficult, it is very difficult." (27)	Feel close to my relative
I would like it if others tried harder to understand the situation I'm in	"We try to explain it to the family, which they don't understand" (23)	Feel connected to the people around me
Nobody can care for the person as well as I can	"I just thought nobody could do it like I could" (10)	Feel in control
I have enough time to myself	"I'm constantly churning it, and I crave time by myself. Sometimes I just go, I'm going upstairs and I just, but then he just keeps appearing" (03)	Freedom
I worry about the safety of the person I care for	"So you know, I refrained from going long distances with him, for safety rather than anything else." (10)	Protect my relative
I don't take very good care of myself	"I don't even get a chance to go to the doctor's so I don't know, I've got high cholesterol but I don't know, I'm thinking at the moment I've probably got high blood pressure, I don't know, so I've not had anything checked, I just neglect myself really" (42)	Take care of myself
Almost all of my conversations are about dementia or caring	"You lose contact really and you find yourself... the only thing you tend to talk about is mum, not you. Whether that's normal I don't know, as a carer whether that's normal or not I've no idea." (21)	Share/express my thoughts and feelings
I have to overcome a lot	"It's getting the red tape out of the way" (34)	Get things done

of ‘red tape’ when sorting things out for the person I care for		

NB The thematic analysis was not directly associated with scale development. Nonetheless items were checked for spread against the themes of the needs-led framework to add to confidence that the item pool comprehensively reflected all key areas of impact of caring on quality of life. For further detail of the sub-themes see Pini et al. 2017 [36].

Table 2: Characteristics of carers who completed qualitative and cognitive interviews

	Qualitative interview sample (n=42)	Cognitive interview sample (n=22)		Qualitative interview sample (n=42)	Cognitive interview sample (n=22)
Gender			**Education**		(Missing = 2)
Female	28	17	Up to 18 years or younger	21	10
Male	14	5	Beyond 18 years	21	10
Ethnicity			**Relationship to person with dementia**		
White	33	16	Wife	12	9
Asian	4	2	Husband	10	5
Black	4	3	Daughter	14	7
Other	1	1	Son	4	0
			Grand-daughter	1	1
Age group			**Location of home**		
25-65 years	24	12	Urban	29	21
65-79 years	15	8	Rural	13	1
80 years +	3	2			

Table 3: The pool of 70 self-reported outcome items to capture the impact of caring for a relative with dementia on the carer's quality of life.

SIDECAR item pool
I have to overcome a lot of 'red tape' when sorting things out for the person I care for
I spend a lot of time trying to sort out services
Little things add up to make caring difficult
I find it hard to switch off from my caring responsibilities
I often feel I want to escape my caring responsibilities
I have enough time to myself
I use services (e.g. respite care, day care, "sitters") to give me a break
I can't travel far in case a crisis arises with the person I care for
Everything I do has to be planned in advance now
I worry about what people think of the behaviour of the person I care for
It is hard to decide what to tell others about the person's dementia
I worry about the safety of the person I care for
Most people around me recognise what I do as a carer
People see me only as a carer rather than a person in my own right
Other people are critical of the way I provide care
Caring has made my social life difficult
I feel other people care about me
I would like it if others tried harder to understand the situation I am in
I ignore my own health needs
The stresses of caring make me think about harming myself
I am not in control of my emotions
I am always tense
I rarely have a good night's sleep
I don't take very good care of myself
I regularly have to do things as a carer that I am not comfortable with
I get help from people who know a lot about how to care for someone with dementia
I worry about what will happen if I can no longer provide care
I dread the future
I can only get through one day at a time
I have been given clear information about finances (e.g. benefits, financial planning)
Receiving help is more hassle than it is worth
I have planned for when things get worse

I have to cope with a lot of opinions about what I should and shouldn’t do
Nobody can care for the person as well as I can
I receive all the support I need to help me provide care
There is always something new to deal with when providing care
I have been given clear information about medical issues (e.g. diagnosis, managing medications)
I have been given clear information about how to make future plans (e.g. care arrangements if circumstances changed, power of attorney)
I feel the good things we have won't last
I have been given clear information about social care for the person I care for (e.g. adult social care services)
I have been given clear information about support available to me as a carer
I worry about our future financial situation
I am well supported by medical professionals (eg GPs, psychiatrists)
I have enough guidance to know how to provide care (e.g. managing difficult behaviours, providing activities)
The support I receive meets my expectations
Almost all of my conversations are about dementia or caring
I am willing to ask for help if I need it
I don't trust anyone with my true feelings about caring
I am not sure when to correct the person I care for and when to go along with them
It is hard to know when to help the person I care for and when to let them do things on their own
It is distressing when I have to upset the person I care for to do the right thing for them
It is hard to find anyone else to spend time looking after the person I care for
I often lose my temper with the person I care for
I have distressing arguments with the person I care for
I find it hard to understand how dementia affects the person I care for
It is distressing to the see the person I care for changing
We have fewer opportunities for closeness now
My role in our relationship (e.g. as spouse, or as child) has changed
I feel close to the person I care for
I struggle to communicate with the person I care for
We have found new activities to share together
I provide the person I care for with good experiences
I've had to put my own life on hold
I never get things right in the way I provide care

My life now is much worse than it was before I was caring
I feel guilty that I don’t give good enough care
Caring has given me a purpose in life
Caring prevents me from fulfilling my other responsibilities, e.g. working, being a parent, volunteering
I feel guilty if I do something for myself
I feel I am doing a good job as a carer

Supplementary material: Item reduction 2, Excel spreadsheet showing process of review leading to rewording or removal of items from the pool.

Cognitive interview items	Feedback from interviews 1-8.	Discussion/changes after 8 interviews	Feedback from interviews 9-16	Discussion + decision after 16 interviews	Items to take forward to interviews 17-22	Feedback from interviews 17-22	Discussion and decision after 22 interviews.	Items to take forward to two rehearsal interviews	Feedback from 2 full rehearsals	Final decision on whether to retain in pool
Reworded items										
It is hard to persuade others to spend time with the person I care for	Not sure persuade is the right word		Didn't like the word persuade. She was trying to say something about how she worried about others not coping with spending time with her mum.	2/6 don't like 'persuade'. **Change to ' It is hard to find anyone else to spend time looking after the person I care for'**	It is hard to find anyone else to spend time looking after the person I care for			It is hard to find anyone else to spend time looking after the person I care for		Keep
Those around me recognise what I do as a carer	(i) Some do, some don't. (ii) Add "overall"	**Change to ' Most people around me recognise what I do as a carer' to get a judgement on the overall position**			Most people around me recognise what I do as a carer			Most people around me recognise what I do as a carer		Keep
I have to cope with a lot of different people's opinions about what I should and shouldn't do	Just one person had opinions, so it was not "a lot"	**Change to 'I have to cope with a lot of opinions about what I should and shouldn't do' to avoid issue of how many people are being referred to, yet retain essence of the item.**			I have to cope with a lot of opinions about what I should and shouldn't do			I have to cope with a lot of opinions about what I should and shouldn't do		Keep
People care about me	(i) Who do we mean by 'people'? (ii) Asked who we meant by 'people'	**Changed to 'I feel cared for' to avoid problems with word 'people'**	Would depend who we were talking about. She struggled to understand what we were asking here and preferred "I feel cared about"	**Change to 'I feel cared for'**	I feel cared for	(i) Really made him stop in his tracks (ii) Thought we were asking about PWD	Review - a couple of people have thought this was about PWD. **Change wording once more to 'I feel other people care about me'**	I feel other people care about me		Keep
Items removed during the stage of 'item reduction 2'										
I have lost the person I once was	(i) Found this very difficult to understand Needs re-wording - doesn't make sense **Context** (ii) Easy to understand but not sure this is connected with caring		(i) Was a little confused by this, but after thinking about it was happy to answer (ii) Thought this was age related (iii) She had to use the word "identity" to understand this item (iv) Thought we were asking about PWD. (v) Thought we were asking about PWD.	Causes confusion. 7/16 have commented. 2 think it is not related to caring. 5 are confused about what it is asking. This is a problem. Hard to think of any way of re-wording. **Remove**						Removed after 16 interviews - meanking is ambiguous.
Using trickery to get the person I care for to do things makes me feel bad	(i) Prefers coaxing - trickery sounds dishonest (ii) Wording - doesn't like 'trickery' sounds too negative/ deceptive (iii) Wording - not sure about the word trickery but it does sum up what you have to do - thought cajoling or coaxing were suitable alternatives (iv) Asked specifically about use of word 'trickery' - thinks it is fine and necessary as it leads to guilt.	Noted 2 comments suggesting trickery was not the right word but 2 others supporting its use. Therefore **keep in and monitor.**	(i) Had to explain this to her. She found it hard to understand because she had not had this experience. (ii) She did not understand trickery. She could not answer until I offerred an alternative "Sometimes I have to trick the person I care for into doing things, which makes me feel bad" (iii) She thought trickery was exactly the right word here	6 comments on 16 responses. Maybe we can simplify to "Having to trick the person I care for into doing things makes me feel bad" or "I often have to trick the person I care for into doing things" **Change to ' "Having to trick the person I care for into doing things makes me feel bad"**	Having to trick the person I care for into doing things makes me feel bad			Having to trick the person I care for into doing things makes me feel bad		Remove - two part question
I find it extremely difficult to deal with physical violence from the person I care for					I find it extremely difficult to deal with physical violence from the person I care for	(i) Disagree because it is not a problem they have (ii) Disagree because it is not a problem they have -		I find it extremely difficult to deal with physical violence from the person I care for		Remove - two part and also dependent on the function of the person with dementia

Sorting out relationships my family members have with each other is a hassle I could do without	(i) I had to explain this item. (ii) I had to explain this item (iii) Wasn't sure about the wording. Suggested "an added burden" instead of "hassle".	Noted potential problems with word 'hassle' but decided to keep in at this stage and monitor.	Found this one hard to grasp and thought we needed to simplify. We used words like "family falling out" and "getting on with each other"	It is causing confusion. Try new wording - including ref to care. **Change to: "Sorting out family disgreements about care is an added burden'**	Sorting out family disagreements about care is an added burden	This is better wording	Review - The new wording is better, but I feel we have a few overlapping items with this one - dealing with opinions, wishing others understood etc.**Keep**	Sorting out family disagreements about care is an added burden	Wasn't sure how to answer this as she did not have disagreements (Participant 52)	Remove - two part question
I fear what might happen if I am honest with services (e.g. my relative might be taken away from me)			Preferred "am careful about what I say to services"	**Re-word to: 'I hold things back when talking with services, for fear of what might happpen, (e.g. my relative might be taken away from me)'**	I hold things back when talking with services, for fear of what might happen, (e.g. my relative might be taken away from me)			I hold things back when talking with services, for fear of what might happen, (e.g. my relative might be taken away from me)		Remove - two part question
I want to be more than a carer	Unclear - not sure what it means		(i) Found this wording very confusing. Couldn't answer until I offered an alternative wording "I want to be able to do other things apart from caring", but I'm not sure this is exactly what we mean here. (ii) Described this as wishful thinking	3/6 comments so definitely problematic as it is. Check it is picked up elsewhere before making a final decision. Undecided. **Leave in and keep an eye on responses.**	I want to be more than a carer			I want to be more than a carer	Thought this was about doing more as a carer (Participant 53)	Remove - meaning is ambiguous
I spend enough time away from the person I care for					I spend enough time away from the person I care for			I spend enough time away from the person I care for		Remove as only 1/9 anwered this differently from "I have enough time to myself".
I wish I could share my feelings about caring with others	Response format - not easy to answer as Y/N				I wish I could share my feelings about caring with others	Answered "agree" even though she does share her feelings, so she answer incorrectly for her situation	People do not always seem to answer this accurately. Some people seem to agree even though they do share their feelings. **Remove as not reliable in getting a valid response**			Removed after 22 interviews as not reliable in getting a valid response
I never talk about how I feel about caring because people will judge me	(i) Response format - not easy to answer as Y/N (ii) Good question				I never talk about how I feel about caring because people will judge me			I never talk about how I feel about caring because people will judge me		Remove - two part question
It makes me anxious not knowing how the dementia will progress					It makes me anxious not knowing how the dementia will progress		Even though it is an important experience, it may be a unanimously endorsed item.	It makes me anxious not knowing how the dementia will progress		Remove - two part question
I find it hard when I remember things that happen but the person I care for does not	(i) Thinking of events/ shared memories rather than arguments (ii) Made her thinks of past shared events/ memories rather than recent arguments which is how the item came about	Although there were 2 similar comments, they did not invalidate the question so no change made at this point.			I find it hard when I remember things that happen but the person I care for does not		Most people have asnwered this in the same direction so far.	I find it hard when I remember things that happen but the person I care for does not		Remove - two part and also dependent on the function of the person with dementia
I feel I have a duty to care					I feel I have a duty to care	Does feel the duty, but also wants to do it, so duty doesn't feel like the right word to her.	Review - Everyone has agreed to this so far	I feel I have a duty to care		Remove - meaning is ambiguous

I feel I am a burden if I ask for help	2 comments - hard to rephrase, keep as is for now.				I feel I am a burden if I ask for help	Different for different people - Family-Yes Services-No		I feel I am a burden if I ask for help		Remove - two part question
I feel in control of the services or support provided to the person I care for					I feel in control of the services or support provided to the person I care for			I feel in control of the services or support provided to the person I care for		Remove - two part and also close in meaning to other items
Professionals really listen to what I have to say	Who do we mean by professionals?		Felt that "professionals" needed defining.	2/4 query 'professionals'. **Change to "Staff I speak with in services really listen to what I say'**	Staff I speak with in services really listen to what I say			Staff I speak with in services really listen to what I say		Remove - two part and also close in meaning to other items
I have a long list of things I never get around to doing	Can apply to anyone!			Everyone agrees so far.	I have a long list of things I never get around to doing			I have a long list of things I never get around to doing		Remove - Not carer specific and endorsed by everyone
I regularly face new hurdles when caring	Had to explain what we meant		(i) Wasn't sure about hurdles, but didn't have an alternative (ii) Described this a wishful thinking	3/5 query 'hurdles' - should we reword: 'I regularly face new hurdles or difficulties when providing care? **Review this when have 24 responses.**	I regularly face new hurdles when caring			I regularly face new hurdles when caring		Remove - close in meaning to 'There is always something new to deal with when providing care'. Only 1 person has answered the items differently.
I worry about the safety of the person I care for when they are at home					I worry about the safety of the person I care for when they are at home			I worry about the safety of the person I care for when they are at home		Remove - merged with I worry about the safety of the person I care for when they are out and about, to make a generic safety item.
Family and/or friends help me to provide care	(i) Might be ambiguous - family may be different to friends. (ii) Friends and family are different	Noted the issue but decided to keep as is, to avoid proliferatjon of items, especialy as help from either wouldadd to QoL	(i) There is a difference between friends and family (ii) Some do some don't	4 comments out of 8 responses are about distinguishing friends and family, so it needs changing. Could separate into two or say 'None of my family or friends fully understand the situation I am in'. **Separate into two items**	Family help me to provide care and Friends help me to provide care	Feels like a good split		Family help me to provide care and Friends help me to provide care		Remove - two part and overlaps with other items
Family and/or friends don't fully understand the situation I am in	(i) Might be ambiguous - family may be different to friends. (ii) Friends and family are different	Noted the issue but decided to keep as is, to avoid proliferatjon of items, especialy as lack of understanding from either would detract from QoL	There is a difference between friends and family	3 comments from 8 responses o the distinction between friends and family. Could use 'others' or separate. **Separate into two items.**	Family don't fully understand the situation I am in and Friends don't fully understand the situation I am in			Family don't fully understand the situation I am in and Friends don't fully understand the situation I am in		Remove - two part and overlaps with other items
Everything I do takes longer than it used to do					Everything I do takes longer than it used to do			Everything I do takes longer than it used to do		Remove - Not carer specific and endorsed by everyone
A lot of the way I care is learnt through trial and error	(i) Not easy to answer Y/N (ii) Not clear on what we meant here. When I explained it she still struggled to relate it to her experiences.	2 comments - hard to rephrase, keep as is for now.			A lot of the way I care is learnt through trial and error			A lot of the way I care is learnt through trial and error		Remove - endorsed by everyone